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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/805,630

03/14/2001

Phillip Dan Cook

ISIS-4718

2799

32650

7590

04/07/2004

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EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

84.

## Office Action Summary

Application No.

09/805,630

Applicant(s)

COOK ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19 and 34-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 and 34-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. In the instant case, the instant application is a divisional of application 09/115,027

### ***Sequence Rules***

2. It is noted that Applicants have not amended the Brief Description of the Drawings to include the sequence identifiers which correspond to the nucleotide sequences disclosures of 10 nucleobases or more as set forth in Figures 1-2. According to 37 CFR 1.821 through 1.825, Applicants are required to assign a sequence identifier (SEQ ID NO) for every disclosed unbranched nucleic acid sequence of 10 or more nucleotides.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 19, and 34-47 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention, for the reasons of record set forth in the Official Action mailed 10-15-03.

Applicant's arguments filed 1-13-04 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by way of amending claim 19 to more clearly describe the invention. According to Applicant's they believe that the amendment filed 1-13-04 address the points raised in the prior Office Action. However, contrary to Applicant's assertions, Applicant's amendment to claim 19 to recite wherein "the compound being capable of hybridizing to said nucleic acid," does not more clearly describe the relationship between the compound and the nucleic acid to be assayed. As for support of their claim amendment, Applicants cite page 13, line 30, to page 14, line 7, this portion of the specification as filed states that the oligonucleotide compounds of the invention "should be contacted with an oligonucleotide having a sequence that is *capable of specifically hybridizing* with a strand of nucleic acid coding for the undesirable protein." It is noted that the instant amendment to claim 19 recites wherein the compound being "capable of hybridizing" not "specifically hybridizing." Although, the specification as filed provides a very broad definition for the term "specifically hybridizing" on pages 11-12, the scope of the term "hybridizing" is even broader since there is no limitation requiring that the hybridizing be "specific" to the nucleic acid to be assayed.

Moreover, although Applicants have amended claim 19 to recite step (b) "determining if said hybridization has occurred," there is no indication that if hybridization was determined, that said hybridization would indicate that the nucleic acid to be assayed, as defined in the preamble" was identified. It remains that Applicant's claimed method is incomplete since steps recited in the method do not result in the assaying of any particular nucleic acid.

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*Closest Prior Art*

5. It is noted that the compounds of the present invention used in the methods recited in the instant claims were rejected under 35 USC § 103(a) as being unpatentable over Cook et al. in view of Sanghvi et al. during the prosecution of parent application 09/115,027. However, this rejection was withdrawn in view of Applicant's argument that the prior art lacks sufficient motivation for combining the prior art to make the claimed compounds in the exactly claimed form. Moreover, since the compounds recited in the issued patent US 6,242,589 were considered allowable over the prior art, the claimed method of using these compounds is considered free of the prior art.

*Conclusion*

6. Claim 19 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

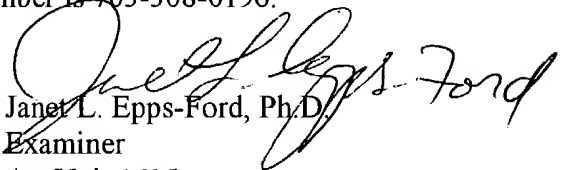
7. Claims 34-47 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Janet L. Epps-Ford, Ph.D.  
Examiner  
Art Unit 1635

*JLE*  
April 5, 2004